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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,583	03/28/2001	Hiroshi Tonoike	OKA-0025	3656

23353 7590 02/21/2003

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/818,583

Applicant(s)

TONOIKE, HIROSHI

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

This Office Action responds the Amendment received on December 11, 2002 (Paper No. 12).

#### *Specification*

The objection to the specification for failing to comply with the Sequence Rules for failing to identify the nucleotide sequences (on page 12) with their proper SEQ ID Numbers, made in the Office Action mailed on September 11, 2002 is maintained for the reasons of record.

Applicants' response received on December 11, 2002 amended the specification to label the nucleotide sequences with "GH20" and "GH21." However, the nucleotide sequences must be identified by their corresponding SEQ ID Numbers.

Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependent claims are rejected for the recitation of the phrase, "directly adding the homogenized sample to a *reaction solution* to amplify the nucleic acid," because it is unclear to what solution the sample is being added to.

#### *Claim Rejections - 35 USC § 102*

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The rejection of claims 1 and 7-11 under 35 U.S.C. 102(b) as being anticipated by Burckhardt (U.S. Patent No. 5,501,963, March 26, 1996), made in the Office Action mailed on September 11, 2002 is withdrawn in view of the Amendment received on December 11, 2002.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-6 and 11 under 35 U.S.C. 102(b) as being anticipated by Steiner et al. (Nucleic Acids Research, 1995, vol. 23, no. 13, pages 2569-2570), made in the Office Action mailed on September 11, 2002 is maintained for the reasons of record.

Applicants' arguments received on December 11, 2002 have been fully considered but they are not found persuasive.

Preliminarily, the instant rejection includes claim 11 which was inadvertently omitted in the previous Office Action mailed on September 11, 2002, resulting from a typographical error. The typographical error is clear in view of what is disclosed in the Steiner et al. reference, wherein the reference states that the sample from which DNA is amplified is a lyophilized tissue (page 2569, 1<sup>st</sup> column) which is a living-body derived sample.

Applicants argue that the method disclosed by Steiner et al. ("Steiner") is directed to extraction of plant samples (pp. 3, response). Applicants assert therefore, that the addition of Steiner's reagents would materially affect the presently claimed homogenized sample, which is

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used for deriving nucleic acids particularly from *animal samples*. No evidence is provided by the Applicants.

To the contrary, Steiner et al. states that their DNA extraction process performed in a single tube can be used for plant, *animal*, and microbial *sources* of DNA (pp. 2569, 1<sup>st</sup> column, 1<sup>st</sup> paragraph).

Therefore based on this evidence, absent evidence to the contrary, the method of Steiner et al. would well anticipate the invention as claimed.

The rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Di-San Junyi Daxue Xuebao, 1999, vol. 21, no.1, Abstract only), made in the Office Action mailed on September 11, 2002 is maintained for the reasons of record.

Applicants' arguments received on December 11, 2002 have been fully considered but they are not found persuasive.

Applicants argue that the storage method of Liu et al. makes no mention of surfactant in its storage medium.

This argument is not found persuasive because the storage medium of Liu et al. comprise SDS-EDTA. According to the definition of on-line Merriam-Webster Collegiate Dictionary (attached hereto), a "surfactant" is defined as a surface-active substance (as a detergent).

As one skilled in the art would readily recognize that SDS is a detergent, Liu et al. would clearly anticipate the method as claimed. In addition, Applicants' claim (claim 5) also defines SDS as a surfactant.

Therefore, the invention as claimed is anticipated by Liu et al.

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***Conclusion***

No claims are allowed.

Claims 7-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim (which overcomes the 112, 2<sup>nd</sup> rejection) and any intervening claims.

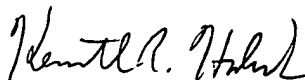
***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

2/12/03



  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

2/13/03